Serial No. 10/071,840

CLAIM AMENDMENTS

1. (Currently amended) An implantable or insertable medical device comprising

(a) bioactive agents comprising (i) an antimicrobial agent and (ii) a microbial attachment/biofilm synthesis inhibitor selected from NSAIDs, chelating agents, and mixtures thereof,

(b) at least one biocompatible matrix polymer region that comprises (i) one or more polymers and (ii) one or more of said bioactive agents dispersed throughout, ~~and (b) bioactive agents comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor~~

wherein said bioactive agents are present in said device in an amount effective to inhibit microbial growth on the device for a period of at least 30 days after implantation or insertion of said device into a subject, and

wherein said medical device comprises at least one biocompatible matrix polymer region that is not a coating.

2. (Currently amended) The medical device of claim 1, wherein both the antimicrobial agent and the microbial attachment/biofilm synthesis inhibitor are present in a single distinct matrix polymer region.

3. (Original) The medical device of claim 1, wherein the antimicrobial agent and the microbial attachment/biofilm synthesis inhibitor are present in distinct matrix polymer regions.

4. (Original) The medical device of claim 1, wherein said antimicrobial agent is present in an amount effective to inhibit the growth of microbes on and around the device and the microbial attachment/biofilm synthesis inhibitor is present in an amount effective to inhibit the attachment of microbes onto and the synthesis and accumulation of biofilm from attached microbes on the surface of the device.

5. (Cancelled)

6. (Currently amended) The medical device of claim 1, wherein said one or more matrix polymers comprise ~~comprises~~ a biocompatible biodegradable polymer.

7. (Currently amended) The medical device of claim 1, wherein said one or more matrix polymers comprise ~~comprises~~ a biocompatible non-biodegradable polymer.

8. (Original) The medical device of claim 7, wherein said non-biodegradable polymer is selected from the group consisting of ethylene vinyl acetate copolymers, copolymers of ethylene with acrylic acid or methacrylic acid, elastomeric polyurethanes and polyurethane copolymers, metallocene catalyzed polyethylene, ionomers and vinyl aromatic copolymers.

9. (Currently amended) The medical device of claim 6, wherein said biodegradable polymer is selected from the group consisting of polylactic acid, polyglycolic acid, and copolymers and mixtures thereof.

10. (Original) The medical device of claim 8, wherein said non-biodegradable polymer is an ethylene vinyl acetate copolymer.

11. (Original) The medical device of claim 10, wherein said ethylene vinyl acetate copolymer has a vinyl acetate content of from about 19% to about 28%.

12. (Original) The medical device of claim 10, wherein said ethylene vinyl acetate copolymer has a vinyl acetate content of from about 3% to about 15%.

13. (Currently amended) The medical device of claim 1, wherein said antimicrobial agent is selected from the group consisting of triclosan, ~~and~~ chlorhexidine and mixtures thereof.

14. (Original) The medical device of claim 13, wherein said antimicrobial agent is

triclosan.

15. (Original) The medical device of claim 14, wherein said microbial attachment/biofilm synthesis inhibitor is selected from the group consisting of NSAIDs, EDTA and EGTA.

16. (Original) The medical device of claim 15, wherein said microbial attachment/biofilm synthesis inhibitor is salicylic acid or a salt or derivative thereof.

17. (Original) The medical device of claim 16, wherein said microbial attachment/biofilm synthesis inhibitor is salicylic acid.

18. (Currently amended) The medical device of claim 4, wherein at least one matrix polymer region comprises ~~the amount of said antimicrobial agent present in said matrix polymer is~~ from about 0.5% to about 25% by weight of the antimicrobial agent. ~~matrix polymer.~~

19. (Currently amended) The medical device of claim 4, wherein at least one matrix polymer region comprises ~~the amount of said microbial attachment/biofilm synthesis inhibitor present in said matrix polymer is~~ from about 0.5% to about 25% by weight of the microbial attachment/biofilm synthesis inhibitor. ~~matrix polymer.~~

20. (Currently amended) The medical device of claim 1, wherein at least one ~~said~~ matrix polymer region ~~further~~ comprises a radio-opacifying agent.

21. (Original) The medical device of claim 20, wherein said radio-opacifying agent comprises bismuth subcarbonate.

22. (Currently amended) The medical device of claim 20 wherein ~~the amount of said radio-opacifying agent present in~~ said matrix polymer region comprises ~~is~~ from about 0.5% to about 45% by weight of the radio-opacifying agent. ~~matrix polymer.~~

23. (Currently amended) The medical device of claim 1, wherein ~~the~~ at least one matrix polymer region further comprises at least one therapeutic agent.

24. (Original) The medical device of claim 23, wherein the therapeutic agent is selected from the group consisting of chemotherapeutic agents, NSAIDs, steroidal anti-inflammatory agents, and mixtures thereof.

25. (Original) The medical device of claim 23, wherein the therapeutic agent is selected from the group consisting of cisplatin, methotrexate, doxorubicin, paclitaxel, docetaxel, dexamethasone, hydrocortisone and prednisone.

26. (Original) The medical device of claim 1, further comprising one or more barrier layers at least partially covering said at least one matrix polymer region.

27. (Original) The medical device of claim 26, comprising a first matrix polymer region; a first polymeric barrier layer at least partially covering an interior surface of said first matrix polymer region; and a second polymeric barrier layer at least partially covering an exterior surface of said first matrix polymer region.

28. (Original) The medical device of claim 27, wherein each of said first matrix polymer region, and said first and second polymeric barrier layers is in the form of an annulus.

29. (Original) The medical device of claim 28, wherein the first and second polymeric barrier layers comprise the same polymeric materials.

30. (Original) The medical device of claim 28, wherein the first and second polymeric barrier layers comprise different polymeric materials.

31. (Original) The medical device of claim 27, further comprising a second and,

optionally, a third matrix polymer region and a third and, optionally, a fourth polymeric barrier layer; wherein the second matrix polymer region is disposed on an outside surface of the second polymeric barrier layer and the third polymeric barrier layer at least partially covers an exterior surface of said second matrix polymer region; and, wherein the third matrix polymer region, when present, is disposed on an interior surface of said first polymeric barrier layer and the fourth polymeric barrier layer at least partially covers an interior surface of said third matrix polymer region.

32. (Original) The medical device of claim 27, wherein the first matrix polymer region comprises an ethylene vinyl acetate copolymer.

33. (Original) The medical device of claim 32, wherein each of the first and second polymeric barrier layers comprises a material selected from the group consisting of metallocene catalyzed polyethylenes and polyethylene copolymers, ionomers, elastomeric polyurethanes and polyurethane copolymers, ethylene vinyl acetate copolymers and copolymers of ethylene with acrylic acid or methacrylic acid.

34. (Original) The medical device of claim 33, wherein the antimicrobial agent is selected from the group consisting of triclosan, chlorhexidine and combinations thereof, and the microbial attachment/biofilm synthesis inhibitor is salicylic acid or a salt thereof.

35. (Original) The medical device of claim 1, wherein the medical device is selected from the group consisting of a stent cover, a biliary stent, a ureteral stent, a pancreatic stent, a urinary catheter, a venous access device, a peritoneal access device, a device connecting or providing drainage between two sterile body environments, and a device connecting or providing drainage between a non-sterile and a sterile body environment.

36. (Original) The medical device of claim 35, wherein the device comprises a device connecting or providing drainage between a non-sterile and a sterile body environment.

37. (Original) The medical device of claim 36, wherein the device comprises a hollow tubular structure.

38. (Original) The medical device of claim 35, wherein the device comprises a stent cover.

39. (Currently amended) The medical device of claim 38, wherein said one or more matrix polymers comprise ~~biocompatible polymeric matrix comprises~~ polyurethane, said antimicrobial agent comprises triclosan, said microbial attachment/biofilm synthesis inhibitor comprises salicylic acid or a salicylic acid derivative and further comprising a bismuth subcarbonate radio-opacifying agent.

40. (Original) The medical device of claim 38, wherein the stent cover comprises a hollow tubular structure adapted to be placed over a stent that comprises a woven, knitted or braided open mesh design comprising a biocompatible material.

41. (Original) The medical device of claim 40, wherein the stent cover is placed over a biliary stent.

42. (Original) The medical device of claim 40, wherein the biocompatible material is selected from the group consisting of stainless steel or a shape memory material.

43. (Original) The medical device of claim 35, wherein the medical device comprises a pancreatic stent that provides drainage from the pancreas to the duodenum.

44. (Original) The medical device of claim 43, wherein the pancreatic stent comprises a buffering agent.

45. (Original) The medical device of claim 44, wherein said buffering agent, upon

exposure to physiological fluids, creates a pancreas-compatible pH level in an environment in which the pancreatic stent is implanted.

46. (Original) The medical device of claim 45, wherein said buffering agent is a bicarbonate salt.

47. (Original) The medical device of claim 46, wherein said bicarbonate salt is selected from the group consisting of sodium and potassium bicarbonate.

48-69. (Cancelled)

70. (Original) The medical device of claim 26, wherein at least one of said one or more barrier layers comprises a biodegradable polymer.

71. (Original) The medical device of claim 70, where said biodegradable polymer is selected from the group consisting of polylactic acid, polyglycolic acid and copolymers and mixtures thereof.

72. (Currently amended) An implantable or insertable medical device comprising:

(a) bioactive agents comprising (i) an antimicrobial agent selected from the group consisting of triclosan, chlorhexidine and mixtures thereof and (ii) a microbial attachment/biofilm synthesis inhibitor selected from the group consisting of salicylic acid and salts and derivatives thereof; and

(b) at least one biocompatible matrix polymer region comprising (i) ~~a~~ one or more polymeric materials selected from the group consisting of ethylene vinyl acetate copolymers, copolymers of ethylene with acrylic acid or methacrylic acid, metallocene catalyzed polyethylenes and polyethylene copolymers, ionomers, vinyl aromatic copolymers, elastomeric polyurethanes and polyurethane copolymers, silicones and mixtures thereof; and (ii) one or more of said bioactive agents dispersed throughout, ~~comprising an antimicrobial agent selected from the group consisting of triclosan, chlorhexidine and mixtures thereof; a microbial attachment/biofilm synthesis inhibitor~~

~~selected from the group consisting of salicylic acid and salts and derivatives thereof; and, a radio-opacifying agent selected from the group consisting of bismuth subcarbonate, bismuth oxychloride, bismuth trioxide, barium sulfate, tungsten and mixtures thereof~~

wherein said bioactive agents are present in said device in an amount effective to inhibit microbial growth on the device for a period of at least 30 days after implantation or insertion of said device into a subject,

wherein said medical device comprises at least one biocompatible matrix polymer region that is not a coating, and

wherein the medical device is selected from the group consisting of a stent cover, a biliary stent, a ureteral stent, a pancreatic stent, a urinary catheter, a venous access device, a peritoneal access device, a device connecting or providing drainage between two sterile body environments, and a device connecting or providing drainage between a non-sterile and a sterile body environment.

73. (New) The implantable or insertable medical device of claim 72, comprising a single extruded biocompatible matrix polymer region that comprises said antimicrobial agent and said microbial attachment/biofilm synthesis inhibitor.

74. (New) The implantable or insertable medical device of claim 73, wherein said single extruded biocompatible matrix polymer region corresponds to an annular medical device body.

75. (New) The implantable or insertable medical device of claim 72, comprising (a) an extruded first biocompatible matrix polymer region that comprises said antimicrobial agent and (b) a coextruded second biocompatible matrix polymer region that comprises said microbial attachment/biofilm synthesis inhibitor.

76. (New) The implantable or insertable medical device of claim 72, wherein said medical device selected from a ureteral stent and a urinary catheter.

77. (New) The implantable or insertable medical device of claim 1,

comprising a single extruded biocompatible matrix polymer region, which comprises said antimicrobial agent and said microbial attachment/biofilm synthesis inhibitor.

78. (New) The implantable or insertable medical device of claim 77, wherein said single extruded biocompatible matrix polymer region corresponds to an annular medical device body.

79. (New) The implantable or insertable medical device of claim 1, comprising (a) an extruded first biocompatible matrix polymer region that comprises said antimicrobial agent and (b) a coextruded second biocompatible matrix polymer region that comprises said microbial attachment/biofilm synthesis inhibitor.

80. (New) The implantable or insertable medical device of claim 1, wherein said medical device selected from a ureteral stent and a urinary catheter.